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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/731,741 | 12/10/2003 | Thomas M. Schmitt | 2223-171 | 5362 |

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| EXAMINER |
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LIETO, LOUIS D

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| ART UNIT | PAPER NUMBER |
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1632

DATE MAILED: 09/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/731,741

Applicant(s)

SCHMITT ET AL.

Examiner

Louis D. Lieto

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 June 2006.
 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,4,8,10-17,22 and 24 is/are pending in the application.
 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
 5) ☐ Claim(s) _____ is/are allowed.
 6) ☒ Claim(s) 1,2,4,8,10-17,22 and 24 is/are rejected.
 7) ☐ Claim(s) _____ is/are objected to.
 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
 10) ☒ The drawing(s) filed on 10 December 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
 * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
 Paper No(s)/Mail Date _____.
 4) ☐ Interview Summary (PTO-413)
 Paper No(s)/Mail Date. _____.
 5) ☐ Notice of Informal Patent Application (PTO-152)
 6) ☐ Other: _____.

DETAILED ACTION

Applicant's arguments filed 6/22/2006 have been fully considered but they are not persuasive. The amendment has been entered. Claims 1,2,4,8,10-17,22 and 24 are pending. Claims 18-21,23,25-28 and 44-49 were canceled and claim 1 was amended. Claims 1,2,4,8,10-17, 22 and 24 are currently under consideration. The sections of title 35 U.S.C not included in this office action can be found in a previous office action. An action on the merits follows.

Claim Rejections - 35 USC § 112

The rejection of claims 1,2,4,8,10-17, 22 and 44-46 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement, is withdrawn in view of applicants amendment of claim 1 so as to remove the new matter.

Claims 1,2,4,8,10-17, 22 and 24 are newly rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims have been amended so that they now contain subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The original disclosure fails to recite the limitation of "CD4⁻ CD8⁻ CD25⁺ CD44^{+/-} double negative (DN) cells" (Claim 1). Applicants have not indicated where in the specification **implicit or explicit** support for this limitation can be found. Based on the disclosure as filed a practitioner in the art would not be able to determine that the inventors contemplated the limitation of "CD4⁻ CD8⁻ CD25⁺ CD44^{+/-} double negative (DN) cells" at the time of filing. Further, a key word search of the specification

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fails to find disclosure of these limitations anywhere in the specification as initially filed.

Therefore, since the specification as filed does not contain support for the term "CD4⁻ CD8⁻

CD25⁺ CD44^{+/-} double negative (DN) cells" it is considered to be new matter. See M.P.E.P.

608.04(a). Claims 2,4,8,10-17, 22 and 24 depend from claim 1. This rejection is necessitated by

applicant's amendments to the claims.

Claims 1,2,4,8,10-17, 22 and 24 are newly rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. This rejection is necessitated by applicant's amendments to the claims.

Regarding claim 1, the parenthetical nomenclature renders the claim indefinite because it is unclear whether the limitation(s) following the terms, e.g. (DP) or (DN) are part of the claimed invention. See MPEP § 2173.05(d). Claims 2,4,8,10-17, 22 and 24 depend from claim 1.

Claim 8 recites the limitation "the cells" in claim 1. Claim 1 lists several different kinds of cells, and claim 8 does not differentiate between them. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 103

Claims 1,2,4,8 and 12-15, 17, 22 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Jaleco et al. {Jaleco et al. (2001) J. Exp. Med. 194:991-1001}, in view of

Nakano et al. {Nakano et al. (1994) Science 265:5175} and Tatsumi et al. {Tatsumi et al. (1990) Proc. Natl. Acad. Sci. 87:2750-2754}.

Response to Arguments

Applicant's arguments filed 6/22/2006 have been fully considered but they are not persuasive. Applicant argues that the cited references fail to provide the necessary disclosure or motivation required to teach an *in vitro* system that supports T cell lymphopoiesis using OP9 cells modified to express Delta-like-1 or Delta-like-4.

Applicant provides a detailed analysis in which they set forth limitations present in the specification that they believe differentiates the claimed invention from that disclosed in the teachings of the cited references. However, it is noted the argued limitations present in the specification are not present in the claims as presently drafted. Further, applicants have amended the claims to read specifically on a method of making CD4⁺ CD8⁺ T cells. Jaleco et al. specifically teaches an *in vitro* system to produce CD3⁺ CD4⁺ CD8⁺ T cells (pg. 992, col. 1, pgph 3; pg. 992, Materials and Methods; pg. 995, Table 1). Therefore applicant's amendments to the claims have not differentiated them from the cited prior art but instead now claim specific embodiments rendered obvious by the cited prior art.

Applicant argues that the teachings of the cited prior art do not render obvious claim 22. However, it is again noted that the limitations noted by applicant in the specification are not present in the claims as presently drafted. Further, the claimed system does not initially require any T cells, and claim 22 merely recites "isolating increased numbers of cells of the T cell lineage." This limitation is met simply by the appearance of a single T cell (which Jaleco

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definitely teaches as “the emergence of a de novo cell population coexpressing CD4 and CD8” (abstract)). If T cells appear de novo, that is an increase. Therefore the teachings of the cited prior art render claim 22 obvious.

Further applicant’s arguments in regards to the unexpected advantages of the instant invention are not relevant since the claims continue to encompass subject matter rendered obvious by the cited prior art.

Next applicant argues that there was no motivation for one of ordinary skill in the art to modify the teachings of Jaleco et al. It is again noted that the claims are drawn to an *in vitro* system that produces specific T cell subtypes, including those taught by Jaleco et al. The practitioner would be motivated to use the OP-9 cells taught by Nakano et al because the presence of M-CSF can inhibit the differentiation of ES cells to blood cells other than macrophages. At a minimum a practitioner practicing the teachings of Jaleco et al. would be motivated to use OP-9 cells, transfected with a vector encoding Delta-1, in order to optimize T cell induction and decrease the production of macrophages. This would be especially relevant when studying mouse T cell lymphopoiesis in order to optimize the number of T cells and variety of sub-types induced.

As previously suggested: applicant would be successful in overcoming the above art rejection if they limited the claims to a method of producing mature T cells. Applicant should note that in view of past enablement rejections they should take care to exclude CD3⁺ CD4⁺ CD8⁻ T cells from any specifically claimed embodiments.

No Claims allowed.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Lou Lieto whose telephone number is (571) 272-2932. The examiner can normally be reached on Monday-Friday, 9am-5 pm.

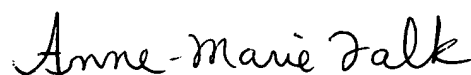
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Ram Shukla can be reached on (571) 272-0735. The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Patent applicants with problems or questions regarding electronic images that can be viewed in the PAIR can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days.

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For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Dr. Louis D. Lieto
Patent Examiner
Art Unit 1632



ANNE-MARIE FALK, PH.D
PRIMARY EXAMINER